LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Att. Kevin Chen
Beijing Lepu Medical Tecnology Co., Ltd
37 Chaoqian Road,
Changping District,
Beijing, 102200
China

9th of april 2021
Case no. 2021034066
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E med-udstyr@dkma.dk

The Danish Medicines Agency hereby authorises Beijing Lepu Medical Technology CO., LTD to place on the market/put into service the SARS-COV-2 Antigen Rapid Test Kit in Denmark.

By consultation procedure letter dated the 8th of April 2021 we asked you to provide any comments to our intended decision.

The Danish Medicines Agency has received a mail from you on the 9th of april stating that you have no comments to the intended decision of the Danish Medicines Agency.

The authorisation is conditional with the following terms and conditions.

Terms and conditions:

- This authorisation is valid until 01.10.2021, or until the date when the device is **CE marked**, if this occurs before 01.10.2021. The manufacturer must inform the Danish Medicines Agency when the CE-mark has been acquired.
- The authorisation is limited to marketing/putting into service in Danish schools and Danish educational institutions.
- If the CE marking has not been achieved 01.07.2021 the manufacturer shall provide a status for the CE marking process.
- **Beijing Lepu Medical Tecnology Co., Ltd** (manufacturer) shall establish a vigilance system, that ensures the collection and reporting to **The Danish Medicines Agency** of any incident, which occurs during the authorisation period.
- The manufacturer must ensure traceability of products through, for example, batch / LOT numbers.
- The information on the labelling and in the instruction for use (IFU) for the "SARS-COV-2 Antigen Rapid Test Kit" shall be in Danish, before distribution to the end-user.
- The labelling must clearly state that the products are placed on the market under this authorization as a derogation from the conformity assessment procedures.
- The test must be accompanied by a detailed IFU, intended specifically for lay people and the intended user group (Danish educational institutions under supervision).
- Technical documentation for the product must be kept for a minimum of 5 years.
- A status shall be provided 01.07.2021 and by the end of this authorization period of how many devices has been placed on the market under this authorization.

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The authorization covers the following product:

Product: SARS-COV-2 Antigen Rapid Test Kit
Catalogue/ Model number(s): CG2701, CG2705, CG2710, CG2725, CG2750
In Vitro Medical Device: General IVD, non-CE-marked for self-testing
Scope: in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens.

Manufacturer of the medical device: Beijing Lepu Medical Tecnology Co., Ltd,
37 Chaoqian Road,
Changping District,
Beijing, 102200
China

Authorised representative for manufacturer: Lepu Medical Cooperatief U.A.
Abe Lenstra Boulevard 36,
8448 JB, Heerenveen,
The Netherlands

Summary of the application of authorisation:

On the 26th of March 2021 Beijing Lepu Medical Tecnology Co., Ltd has applied for an authorisation to place on the market/put into service a non-CE-marked in vitro diagnostic medical device for self-testing by way of derogation from the conformity assessment procedures in the Danish executive order for in vitro medical devices.

The manufacturer has in their application informed The Danish Medicines Agency that SARS-COV-2 Antigen Rapid Test Kit is currently undergoing CE marking for self-testing purposes by the Notified Body TÜV Rheinland, No. 0197, Tillystraße 2 90431 Nürnberg, Germany.

The application states that the tests are intended for use in schools and educational institutions for self-testing under supervision. The manufacturer will supply the products with a Danish IFU.

Reason:

The Danish Medicines Agency can according to section 6, subsection 11 in the Executive Order 1269 of 12. December 2005 on in vitro diagnostic medical devices, under certain circumstances grant an authorization to market and put into service an in vitro diagnostic medical device, for which the procedures referred to in subsections 1 to 4 have not been carried out, for the protection of health.

The Danish Medicines Agency only considers applications if there are clear health reasons and if there are no available alternatives on the market.

In this case The Danish Health Authority has stated, that in the present circumstances related to the Covid-19 situation in Denmark, there is a need for students in Danish schools and educational institutions to be tested on a regular basis by using antigen test for self-testing. This is in order to maintain epidemic control and to contribute to improvement of the mental health of the students so they may return to schools.

The Danish Health Authority has further stated, that it is not possible to organise testing of all students on a regular basis during a longer period, solely by using the present available national test system, where only tests that are CE marked for professional use are used.

After a review of SARS-COV-2 Antigen Rapid Test Kit, Statens Serum Institut (SSI), which is the Danish agency for disease preparedness and surveillance, has stated that based on the data delivered by the manufacturer, the product is sufficient for the purpose of maintaining epidemic control.

It is therefore the Danish Medicines Agency's opinion, that there is a necessity for the protection of health of Danish students and that there are no available alternatives on the market at the present time.

Based on the statement from SSI, it is furthermore the Danish Medicines Agency's opinion, that the product SARS-COV-2 Antigen Rapid Test Kit is sufficient for the purpose of maintaining epidemic control schools and educational institutions for self-testing under supervision.

The Danish Medicines Agency therefore authorizes Beijing Lepu Medical Tecnology Co., Ltd to place on the market/put into service the SARS-COV-2 Antigen Rapid Test Kit in Denmark for the protection of the public health.

Legal basis

Medical devices are regulated in the EU by the Council Directive 98/79/EEC on in vitro diagnostic medical devices. The Directive is implemented in the Danish Executive Order No. 1269 of 12 December 2005 on In Vitro Diagnostic Medical Devices.

This decision is made in accordance with section 6, subsection 11 of the Executive Order on in vitro diagnostic medical devices, that states, that The Danish Medicines Agency, by way of derogation from subsections 1 to 4, may authorise, on duly justified request, the placing on the market and putting into service, of individual devices for which the procedures referred to in paragraphs 1 to 4 have not been carried out and the use of which is in the interest of protection of health.

Appeals procedure
This decision may be appealed to Danish Ministry of Health, Holbergsgade 6, 1057 København K, sum@sum.dk.

The Danish Medicines Agency will take its final decision after the end of the consultation period.

Sincerely

Thomas Wejs Møller
Head of Unit

Jeppe Larsen
Head of Section